K024009
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Trade Name: CryoProbe™

Common Name: Unit, Cryosurgical, Accessories

MAR 2 0 2003

Classification: 878.4350 Cryosurgical Unit, Class II

Predicate Devices:

a) Wallach Surgical Ultra Freeze and Cold Soaker
b) Erbokryo CA Cryosurgical System

Device Description:

The CryoProbe™ is a hand-held cryosurgical instrument for destroying tissue during surgical procedures by applying extreme cold gas (N2O). The device is based on direct application of nitrous oxide in the liquid phase to the selected area. The N2O gas is delivered to the treatment site at -89° C to effect cellular destruction.

The hand-held device is shaped like a pencil to afford maximum user control and comfort. An N2O gas cylinder, commercially available, is held within the pencil body. The gas cylinder is punctured at its intended nozzle by the CryoProbe™ gas guidance tube and retained by the safety valve (handle) until treatment begins. The gas flow is controlled by the microapplicators, high or low flow. This flow rate is selectable when a gas cylinder is installed by selecting the appropriate microapplicator for the assembly.

The CryoProbe™ is designed for safety, performance, and convenience for the user. The design is confirmed by Risk Analysis and actual market usage in the European market. Over 3,000 units are in distribution and use with no adverse effects reported.

Intended Use:
To destroy tissue during surgical procedures by applying extreme cold.

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510(k) Summary

H&O Equipments NV/SA
Ninovesteenweg 198
9320 Aalst (Erembodegem)
Belgium
+32-53-76.17.40 Telephone
+32-53-83.20.04 Fax

Contact Person:
Mr. Lewis Ward
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, CO 80301
303-530-3279 Telephone
303-530-4774 Fax

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

H & O Equipments NV/SA
c/o Lewis Ward
L. W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, Colorado 80301

MAR 2 0 2003

Re: K024009
Trade/Device Name: CryoProbe™
Regulation Number: 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: March 14, 2003
Received: March 17, 2003

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Initial 510(k): K024009

Device Name: CryoProbe™

Indications for Use:

To destroy tissue during surgical procedures by applying extreme cold.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024009

Prescription Use ___X___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)